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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,255	03/27/2006	D Russell Pflueger	QMI-3077 CIP	4881

23410 7590 04/16/2010
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EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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04/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,255	Applicant(s) PFLUEGER ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 104-110 and 125-147 is/are pending in the application.
- 4a) Of the above claim(s) 104-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 104-110 and 125-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 104-110 and 125-147 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/9/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to applicant's amendment filed January 19, 2010. As directed by the amendment, claims 1-103 and 111-124 are cancelled; claims 105-106 have been amended, and claims 125-147 have been added. Claims 104-109 have been withdrawn from consideration as being drawn to a non-elected invention. Thus, claims 125-147 have been treated on the merits.

Election/Restrictions

2. Applicant's election of claims 125-147 in the reply filed on January 19, 2010 is acknowledged. Applicant argues that claims 104-110 are generic to the species identified in the Office Action since claim 104 does not specify whether the at least one element is substantially bow shaped or planar. This is demonstrated by the addition of new claim 125, which recites that the element of claim 104 is "substantially bow shaped when the appliance is at rest." Applicants would like to point out that the embodiments of FIGS. 7-10 can also have a substantially bow or arcuate shape and therefore also should fall within the elected species.

3. Although the examiner agrees that newly added claims 125 and 126 read on the elected invention, claim 104 is not generic to the elected invention, as the elected invention was drawn to an **apparatus and method of using an apparatus comprising an appliance having at least one element being substantially bow shaped with the appliance at rest**. Thus, claims 125 and 126 have been considered as they read on the elected invention and claims 104-109 have been withdrawn from consideration.

Information Disclosure Statement

4. The information disclosure statement filed August 11, 2006 fails to comply with 37 CFR 1.98(a)(2), **which requires a legible copy of each cited foreign patent document**; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information lined through has not been considered.
5. The information disclosure statement filed August 11, 2008 fails to comply with 37 CFR 1.98(a)(3) **because it does not include a concise explanation of the relevance**, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information lined through has not been considered.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 147 is rejected under 35 U.S.C. 102(b) as being anticipated by Patil et al. (5,720,275).

Patil discloses a method for maintaining the patency (affording free passage) of an airway of a patient comprising: introducing an appliance (10) into an oropharyngeal region of the patient (figures 2-5), the appliance comprising a transverse portion (middle

portion of 14) between spaced apart ends (18 & 33), the transverse portion (middle portion of 14) being substantially bow shaped with the appliance at rest; and securing the appliance within the oropharyngeal region such that the transverse portion extends at least partially around the oropharyngeal region and the end portions push the tongue forward to hold the airway patent. See: figures 2-5.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 125-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metzger et al. (2003/0149488) and further in view of Zammit (6,328,753).

Metzger discloses a method of treating snoring by sleep apnea and snoring in a human which has an oropharyngeal region with lateral and posterior walls (figure 5), the method comprising: providing an appliance (110) comprising at least one element (combined portions of 112) having a length extending from a first end (tip of 112) to a second end (tip of opposite 112), the appliance (110) comprising a central body portion (mid portion between first and second 112) between end portions adjacent the first and second ends; inserting the appliance into an oropharyngeal region (figure 6, 8, 9 & 11) so that the central body portion extends generally laterally across the posterior wall and the end portions support the lateral walls of the oropharyngeal region, wherein the at least one element (112) is substantially bow shaped with the appliance at rest.

However, Metzger lacks applying the appliance in a constrained configuration; and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to expand radially within the oropharyngeal region.

Zammit teaches an appliances (1) that is a used for treating snoring that is held in a constrained configuration (figure 6) and then expands radially when the appliance is released (figure 7).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating apnea and snoring, as disclosed by Metzger, by using an appliance with a collapsed configuration which could be more easily positioned within the user's airway, and then released the device thereby allowing the device to expand in the desired location, as taught by Zammit, because of the reasonable expectation of obtaining a method of treating snoring and sleep apnea with a device that would provide easier manipulation of the appliance into the patients airway.

Regarding claim 126, the at least one element discloses by Metzger is pre-curved and a change in the size of a prior art device is a design consideration within the skill of the art. Moreover, the diameter being larger than the oropharyngeal region is dependent upon the patient being treated, as same device used on differently sized patients may have a larger diameter than the oropharyngeal region on one patient (infant) and a smaller diameter than the oropharyngeal region on another patient (adult). However, the device of the combined references, in the constrained condition, has the

at least one element (112 of Metzger) sized for introduction into the oropharyngeal region of a patient.

10. Claims 127, and 130-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. (2003/0149445) and further in view of Patil et al. (5,720,275).

Knudson discloses a method of treating sleep apnea and snoring, comprising: introducing an appliance (20 & 22) into an oropharyngeal region of a patient (figure 10, 11), the appliance (20 & 22) comprising a transverse portion (middle portion of 20 & 22) between end portions (end portions of 20 & 22), the transverse portion (middle portion of 20 & 22) being substantially bow shaped (figures 10 & 11) with the appliance at rest; and securing ([0059]-[0063]) the appliance within the oropharyngeal region such that the transverse portion (middle portion of 20 & 22) extends along a posterior wall and at least partially around opposite lateral walls of the oropharyngeal region0

However, Knudson lacks teaching the end portions support the tongue.

Patil teaches device (14) that in use is positioned so that it extends along a posterior wall and at least partially around opposite lateral walls of the oropharyngeal region and the end portions support the tongue. See: figures 1-3 and 5.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating snoring and sleep apnea, as disclosed by Knudson, by using a device that provides a good anatomical fit, because of the reasonable expectation of obtaining a method of treating snoring and sleep apnea with a device that can be quickly and easily inserted into the mouth of

patient without concern for inadvertently directing the device into the patient's esophagus.

11. Regarding claims 130-131, the appliance disclosed by the combined references, by virtue of its anatomical fit, would provide a substantially constant radial force against the lateral walls of the oropharyngeal region and the base of the tongue.

Regarding claim 132, the appliance disclosed by the combined references, is secured within the oropharyngeal region such that the end portions extend around opposite lateral walls of the oropharyngeal region and support the tongue. See: figures 1-3 and 5 of Patil.

Regarding claims 133-134 it appears the device of the combined references, when placed in the user's body as described by Patil would, upon contraction of the oropharyngeal region have the end portions temporarily forced towards one another, and the end portions would be biased to their original configuration which is move away from one another back to the open configuration when placed inside the oropharyngeal region and the end portions would push the tongue forward to hold the airway patent; particularly since Patil discloses forming the device of silicone or rubber or any other atraumatic, elastomeric or moldable material. See: col. 2, last paragraph of Patil.

Regarding claim 135, the appliance disclosed by the combined references extends around the airway such that the end portions traverse a base of the tongue. See: figures 1-3 and 5 of Patil.

Regarding claims 135 & 136 Knudson discloses securing means using adhesives [0057]-[0063] and sutures [[0075] and it would have been obvious to the skilled artisan

to utilize adhesive or sutures to maintain the appliance in a desired location because these are both well known securing techniques in the art.

Regarding claim 138, Knudson discloses the use of micro-needles (30 of figure 8) attached to the appliance for injecting adhesives and micro-beads into the tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used micro-needles on the appliance of the combined references, in order to form strong adhesion between the appliance and the tissue of the patient.

12. Claims 125-126; 128-129 and 139-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudson et al. (2003/0149445) and Patil et al. (5,720,275), as applied to claim 127 above, and further in view of Zammit (6,328,753).

The combined references disclose all the limitations of claims 125, 128-129 and 139 except inserting the appliance into an oropharyngeal region in a constrained configuration; and releasing the appliance within the oropharyngeal region, thereby allowing the appliance to expand radially within the oropharyngeal region so that the central body portion extends generally laterally across the posterior wall and the end portions support the lateral walls of the oropharyngeal region.

Zammit teaches an appliances (1) that is a used for treating snoring that is held in a constrained configuration (figure 6) and then expands radially when the appliance is released (figure 7).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of treating apnea and snoring, as disclosed by the combined references by using an appliance with a collapsed

configuration that could be more easily positioned within the user's airway, and then releasing the device thereby allowing the device to expand to its desired configuration in a desired location, as taught by Zammit, because of the reasonable expectation of obtaining a method of treating snoring and sleep apnea with a device that would provide easier manipulation of the appliance into the patients airway.

Regarding claim 126, the at least one element discloses by the combined references is pre-curved and a change in the size of a prior art device is a design consideration within the skill of the art. Moreover, the diameter being larger than the oropharyngeal region is dependent upon the patient being treated, as same device used on differently sized patients may have a larger diameter than the oropharyngeal region on one patient (infant) and a smaller diameter than the oropharyngeal region on another patient (adult). However, the device of the combined references, in the constrained condition, has the at least one element sized for introduction into the oropharyngeal region of a patient.

Regarding claims 140-143, see the rejection of claims 129-132 above.

Regarding claims 144-145, see the rejection of claims 135-136 above.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Metzger et al (7,017,582); Grosbois et al (6,474,339); Knudson et al. (2005/0268919) which all disclose treatments for snoring and apnea.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771